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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,137

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Christian Schlatter

70322/UST

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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

02/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

department-gso.patent@syngenta.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,137	<b>Applicant(s)</b> SCHLATTER ET AL.	
	<b>Examiner</b> KATHERINE ZALASKY	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060418</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of imidicloprid and metalaxyl as the pesticide species and acetonitrile as the extracting fluid species in the reply filed on 10 December 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. All claims are currently generic; therefore, all claims will be examined at this time.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 18 April 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Therefore, Document RU-2034295-C1 has not been considered.

### ***Claim Objections***

4. **Claim 1** is objected to because of the following informalities: it is suggested to replace "pesticidally treated" with "pesticide treated".

5. **Claim 5** is objected to because of the following informalities: although it is understood that the recitation of "at most 150mm x 4.6mm diameter" is referring to the dimensions of the chromatography column, it is suggested to label both the length and diameter values. A suggested correction may be to replace "at most 150mm x 4.6mm diameter" with "a length less than 150mm and a diameter less than 4.6mm". Further, in line with this reasoning, it is suggested to replace "at most 5 micron packing" with "a packing having a diameter less than 5 microns". Appropriate correction is required.

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### ***Claim Interpretation***

6. It is noted that the inclusion of "optional" language in a claim is not deemed to limit the claim in any manner. Therefore, any such language in the claims will be disregarded from the claim (i.e. "optionally then combine the test samples").

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 1 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huijbregts et al. ("Fungicides and insecticides applied to pelleted sugar-beet seeds – I. Dose,**

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distribution, stability and release patterns of active ingredients”) in view of McDonald (“Single-Classification ANOVA: Introduction”) and Mateos et al (US 3,996,132) or Kohn et al. (US 5,405,782).

Regarding **claim 1**, Huijbregts et al. discloses a method for determining the single seed loading distribution of two or more pesticides on pesticide treated seeds comprising the steps of (1) Selecting a subset of seeds sufficient to determine said distribution, (2) Maintaining a seed from said subset in contact with an extracting fluid to substantially selectively extract one or more pesticides from said seed to yield a test sample, (4) Separating the one or more pesticides from other substances in the test sample by chromatography, (5) Passing the one or more separated pesticides into a detector, (6) Detecting the signal generated by the pesticide at the detector (pg 355/C2, pg 366/C1, Table 1):

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## **Materials and methods**

### **Treatments**

Fungicides (thiram and hymexazol) and insecticides (methiocarb, carbofuran, furathiocarb, benfuracarb, carbosulfan, tefluthrin and imidacloprid) were applied to pellets at different doses by various pelleting companies according to their own processes (Betakote, Cermer, Germain's EB, KWS, Maribo, Sarea and SUET).

### **Mean loading of active ingredients in pelleted sugar-beet seed lots**

Two representative samples, usually containing 100 pellets each, were analysed to determine the mean concentration of active ingredients in a sugar-beet seed lot. The analyses are based on extraction of the active ingredients with 100 ml suitable organic solvent and subsequent determination by High Performance Liquid Chromatography (Table 1). Concentrations are expressed as grams active ingredient per 100 000 seeds (g a.i./unit).

### **Distribution of active ingredients between individual pellets**

For the determination of variation of active ingredients between individual pellets of the same lot, at least 20 pellets were analysed individually, using the same method as described (Table 1) with 3 or 5 ml extraction solvent for each pellet.

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Table 1. Schematic survey of extraction and determination of active ingredients in pelleted sugar-beet seed

Active ingredient	Extraction solvent	stationary phase	HPLC column: l = 250 mm; i.d. = 4.6 mm Flow: 1.5 ml/min	
			mobile phase	UV-detection $\lambda$ (nm)
thiram methiocarb furathiocarb benfuracarb carbosulfan carbofuran	acetone	Lichrosorb Si 60-5	chloroform/ hexane (35/65)	270
tefluthrin	acetone	Spherisorb 5 ODS-2	acetonitril/ water/1% $H_3PO_4$ (80/15/5)	270
hymexazol	acetonitril/ water/1% $H_3PO_4$ (15/80/5)	Spherisorb 5 ODS-2	acetonitril/ water/1% $H_3PO_4$ (15/80/5)	240
imidacloprid	acetonitril	Spherisorb 5 ODS-2	acetonitril/ water/1% $H_3PO_4$ (50/45/5)	240

Additionally, the reference discloses the following steps: (7) Relating the amount of signal detected to a quantity of pesticide, (8) Repeating steps 2-7 sequentially for each seed in said subset, (9) Determining the single seed loading distribution for the pesticide treated seeds based on the pesticide quantity determined for each seed in the subset (pg 355/C2, pg 366/C1-2, Table 1, remainder of tables in reference show calculated concentrations of pesticides from seeds):

#### Statistical analysis

The F-test (Gore, 1952) was used to determine differences between variations in loading of pesticides in individual pellets.

The data of the release experiments were analysed using ANOVA methods (Mead and Curnow, 1983). The means were separated using the least significant difference (LSD) test.

However, while the reference discloses that the normal (Gaussian) distribution is calculated (F-test, ANOVA), it does not state that the non-Gaussian distribution is calculated.

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Further, the reference does not disclose the step of (4) Filtering the test sample containing the pesticide to substantially remove undesired substances extracted from the seed.

McDonald discloses information on the ANOVA method of statistical analysis (pg 1/¶1). Additionally, the reference discloses that if the data does not the assumptions of the ANOVA (i.e. normality/Gaussian), that it is appropriate to do a non-parametric (non-Gaussian) test as well (pg 1/¶4).

It would have been obvious to one having ordinary skill in the art at the time of the invention to perform a non-Gaussian statistical analysis on the data collected in the method of Huijbregts et al., as taught by McDonald, since doing so will ensure proper analysis of the data and since doing amounts to nothing more than the combination of known prior art steps according to known methods in order to achieve predictable results.

Mateos et al. discloses a method of preparing samples for liquid chromatography which includes a step of solvent extraction (C2/L23-30), a step of filtration (C2/L45-54) and a step of chromatographic separation (C2/L64-68). Additionally, Kohn et al. also discloses that it is known in the art of chromatographic separations to use solvent extraction to obtain a sample, filter the sample to remove any particulate matter and then perform chromatography on the sample (C1/L19-34).

It would have been obvious to one having ordinary skill in the art at the time of the invention to filter the extracted sample prior to the step of chromatography in the method of Huijbregts et al., as taught by Mateos et al. or Kohn et al., since doing so amounts to nothing more than the combination of known prior art methods according to known methods in order to achieve predictable results. Additionally, a step of filtration will ensure that no particulate matter enters the chromatography column, an event which one of ordinary skill in the art would recognize as being incapacitating to the column.



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Regarding **claim 4**, modified Huijbregts et al. discloses all of the claim limitations as set forth above. Additionally, while the reference discloses that different UV wavelengths are used for different compounds (Table 1, 270nm and 240nm), Huijbregts et al. does not disclose that the UV is operated at 265nm and 230nm. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to optimize the wavelengths used in the UV-Vis detector, through routine experimentation, which produce the best signals for each targeted compound.

Regarding **claim 5**, modified Huijbregts et al. discloses all of the claim limitations as set forth above. Additionally, Huijbregts et al. discloses that the HPLC is performed on a column with a length of 250mm, a diameter of 4.6mm, and which is filled with a packing of 5 micron diameter (Table 1, Spherisorb 5 ODS-2 is 5 microns in diameter). Since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the length of the column, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

11. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Huijbregts et al. ("Fungicides and insecticides applied to pelleted sugar-beet seeds – I. Dose, distribution, stability and release patterns of active ingredients"), McDonald ("Single-Classification ANOVA:

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Introduction”) and Mateos et al (US 3,996,132) or Kohn et al. (US 5,405,782), as applied to claim 1 above, and further in view of Hutchins et al. (US 4,835,711).

Regarding **claim 2**, modified Huijbregts discloses all of the claim limitations as set forth above. While Huijbregts et al. discloses that 3 to 5 ml of extracting solvent are added to the individual seeds for pesticide extraction (pg 355/C2, pg 366/C1, Table 1), the reference does not disclose that this step is performed by an autodiluter.

Hutchins et al. discloses a robotic system which may be used to provide an automated processing system wherein the apparatus is more quickly and easily set up for running sequences of an automated process (C2/L8-11) and which may be used in liquid chromatography applications where the instrument adds extracting solvent to vials (C11/L12-21).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use an autodiluter to add the extracting solvent to numerous vials in the method of modified Huijbregts, as taught by Hutchins et al., since doing so will add a simple and easy to set up, automated element to the process. Additionally, the modification amounts to nothing more than the combination of known prior art elements according to known methods to achieve the predictable result of added automation.

12. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Huijbregts et al. (“Fungicides and insecticides applied to pelleted sugar-beet seeds – I. Dose, distribution, stability and release patterns of active ingredients”), McDonald (“Single-Classification ANOVA: Introduction”) and Mateos et al (US 3,996,132) or Kohn et al. (US 5,405,782), as applied to **claim 1** above, and further in view of Classon et al. (US 5,567,309).

Regarding **claim 3**, modified Huijbregts discloses all of the claim limitations as set forth above. While the above combination includes the steps of solvent extraction, filtering and

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chromatographic separation, the references do not disclose that the filtering takes place in an autosampler vial with a built-in filter.

Classon et al. discloses a self-filtration cap for autosampler vials which can be used prior to liquid chromatography separations (abstract). This device has the advantages of providing a fully automatic, economical, single-use filtration device with a thin filter having a large surface area and which has minimum sample retention in the filter (C3/L1-9, C2/L58-67).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use an autosampler vial which has a filter in the cap thereof in the method of modified Huijbregts, as taught by Classon et al., since doing so would provide a fully automatic and economical filter in the method which has minimum sample retention and eliminates the need for a separate filtering stage. Additionally, the modification amounts to nothing more than the combination of known prior art elements according to known methods to achieve the predictable result of added automation.

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on 7:00am - 12:00m Monday and Friday and 7:30am - 6:00pm Tuesday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

/KZ/  
1 February 2010